# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: ISPH-0501

Inventors: Baker et al.

Serial No.: Not yet assigned

Filing Date: Herewith

Examiner: Not Yet Assigned

Group Art Unit: Not yet assigned

Title: Antisense Oligonucleotide

Modulation of Tumor Necrosis

Factor- $\alpha$  (TNF- $\alpha$ )

Expression

"Express Mail" Label No. **EL976562751US** Date of Deposit <u>August 26, 2003</u>

I hereby certify that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner for Patents, Mail Stop Sequence, P. O. Box 1450, Alexandria, VA 22313-1450.

By <u>francisculate</u>
Typed Name: Jane Massey Licata, Reg, No. 32,257

Commissioner for Patents Mail Stop Sequence P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

#### INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §\$1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

- (XX) In accordance with §1.97(b), since this Information

  Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, no additional fee is required.
- ( ) In accordance with \$1.97(c), this Information Disclosure Statement is being filed after the period set forth in \$1.97(b) above but before the mailing date of either a Final Action under \$1.113 or a Notice of Allowance under \$1.311, therefore:
  - ( ) Certification in Accordance with §1.97(e) is set forth below; or
  - ( ) The fee of \$240.00 as set forth in \$1.17(p) is attached.
- ( ) In accordance with \$1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under \$1.113 or a Notice of Allowance under \$1.311 but before the payment of the Issue Fee, therefore included are: Certification in Accordance with \$1.97(e); Petition Requesting Consideration of the Information Disclosure Statement; and the fee of \$130.00 as set forth in \$1.17(I)(1).
- ( ) Copies of each of the references listed on the attached Form PTO-1449 (modified) are enclosed herewith.

(XX) In accordance with §1.98(d), copies of some or all of the references listed on the attached Form PTO-1449 (modified) are not enclosed herewith because they were previously submitted to the U.S. Patent and Trademark Office in prior application Serial No. 09/824,322 filed April 2, 2001, 09/313,932 filed May 18, 1999, and Serial No. 09/166,186, filed October 5, 1998, for which a claim for priority under 35 U.S.C. §120 has been made in the instant application.

Please charge any deficiency or credit any overpayment to Deposit Account No. 50-1619. This form is submitted in duplicate.

- ( ) The relevance of the listed references in a foreign language is as stated in the specification at pages @@.
- (XX) All listed references are in the English language.

Respectfully submitted,

Jan hossylecte

Jane Massey Licata Registration No. 32,257

Date: August 26, 2003

Licata & Tyrrell P.C. 66 E. Main Street Marlton, New Jersey 08053

(856) 810-1515

### Sheet **01** of **03** Docket No. Serial No. Form PTO-1449 Modified ISPH-0767 Not yet assigned List of Patents and Publications Applicant Cited by Applicant BAKER, ET AL. (Use several sheets if necessary) Filing Date Group U.S. Department of Commerce Herewith Not yet assigned OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Aggarwal et al., "Triple Helix-forming Oligodeoxyribonucleotides Targeted AΑ to the Human Tumor Necrosis Factor (TNF) Gene Inhibit TNF Production and Block the TNF-dependent Growth of Human Glioblastoma Tumor Cells1", 1996, Cancer Res., 56, 5156-5164 dHellencourt, "Inhibition of human $TNF\alpha$ and LT in cell-free extracts and in AΒ cell culture by antisense oligonucleotides", 1996, Biochim. Biophys. Acta, 1317, 168-174 AC Hartmann, "Oligodeoxynucleotides Enhance Lipopolysaccharide-Stimulated Synthesis of Tumor Necrosis Factor: Dependence on Phosphorothioate Modification and Reversal by Heparin", 1996, Mol. Med., 2, 429-438 ΑD Hartmann, "Specific Suppression of Human Tumor Necrosis Factor- $\alpha$ Synthesis by Antisense Oligodeoxynucleotides", 1996, Antisense Nucleic Acid Drug Devel., 6, 291-299 Rojanasakul, "Antisense Inhibition of Silica-induced ΑE Tumor Necrosis Factor in Alveolar macrophanges", 1997, J. Biol.Chem., 272, 3910-3914 ΑF Taylor et al., "In Vitro Efficacy of Morpholino-modified Antisense

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Nucleic Acid Drug Devel., 8, 199-205

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Oligomers Directed against Tumor Necrosis Factor-a mRNA", 1998, Antisense

Taylor et al., "Effect of TNF- $\alpha$  Antisense Oligomers on

macrophages", 1996, J. Biol. Chem., 271, 17445-17452

Tu et al., "Tetranucleotide GGGA Motif in Primary RNA

Transcripts", 1998, J. Biol. Chem., 273, 25125-25131

Cytokine Production by Primary Murine Alveolar

### Form PTO-1449 Modified

List of Patents and Publications Cited by Applicant (Use several sheets if necessary)

U.S. Department of Commerce

Docket No. ISPH-0767	Serial No. Not yet assigned		
Applicant BAKER, ET AL.			
Filing Date Herewith	Group Not yet assigned		

# U. S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Subclass
	AA	5,650,316	7-22-97	Aggarwal, et al.	435	375
	<u> </u>					

### FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Transl YES	Translation YES NO	
	AB	WO 93/09813	5-27-93	PCT	X		
	AC	0 414 607 B1	8-22-90	PCT		Х	
	AD	WO 95/33493	12-14-95	PCT	X		
	AE	WO 95/00103	1-5-95	PCT	X		
	AF	WO 95/32628	12-7-95	PCT	X		

EXAMINER DATE CONSIDERED

Sheet **03** of **03** Serial No. Docket No. Form PTO-1449 Modified Not yet assigned ISPH-0767 List of Patents and Publications Applicant Cited by Applicant BAKER, ET AL. (Use several sheets if necessary) Filing Date Group U.S. Department of Commerce Not yet assigned Herewith U. S. PATENT DOCUMENTS Document Class Subclass Examiner Date Name Initial No. FOREIGN PATENT DOCUMENTS Translation Examiner Document No. Date Country YES NO Initial 5-11-94 Χ AG WO 94/10301 PCT WO 95/23225 8-31-95 PCT Χ AΗ EXAMINER DATE CONSIDERED

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